JUL 17 2000

# Attachment C

K001362

# Summary of Safety and Effectiveness

## 510(k) Summary of Safety and Effectiveness

This summary of premarket notification safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92.

Application: Karl Storz Imaging, Incorporated
175 Cremona Drive
Goleta, California 93117

Contact: Mr. Terry Fernandez

Registration: 2027009

Device Name: Proprietary Name -- Karl Storz 3D Video System
Common Name -- Color Television Camera Head
Classification Name -- Camera, Television, Endoscopic

Intended Use: The Karl Storz 3D Camera System ~~is a color television system~~ designed for use in the operating room. The camera head is suitable for attachment to any Karl Storz 3D endoscope. The camera head is coupled to the endoscope ocular by means of a grasping mechanism allowing the endoscopic image to be viewed using standard 3D ancillary items.

Device Description: The 3D Video system takes two endoscopic views from ~~a patient~~ through a single camera lens by alternately shuttering half of the lens, and through signal enhancement and accessory devices allows for a 3 dimensional image to appear on a monitor when viewed through a shutter screen and polarized glasses.

Substantial Equivalence:
KSI 3D Video System is substantially equivalent to KSI's premarket notification number K950862 (three chip) camera, and its 3D applications based on substantially equivalent 3D video systems, the 3D See International Telepresence, premarket notification number K951646 and Intuitive Surgical Inc. 3D camera system, premarket notification number K990188

Signed: _____ Date: 4/27/00
Terry Fernandez

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2000

Mr. Terry Fernandez
Director, Regulatory Affairs
and Standards Compliance
Karl Storz Imaging, Inc.
175 Cremona Drive
Goleta, California 93117

Re: K001362
Trade Name: KSI 3D Video System
Regulatory Class: II
Product Code: GCJ
Dated: April 27, 2000
Received: April 28, 2000

Dear Mr. Fernandez:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Attachment E

# Indication for Use and Prescription Use Statement



510(k) Number (if known): K001362

Device Name: KSI 3D Video System

Indication for Use:

The Karl Storz 3D Camera System is a color television system designed for use in the operating room. The camera head is suitable for attachment to any Karl Storz 3D endoscope. The camera head is coupled to the endoscope ocular by means of a grasping mechanism allowing the endoscopic image to be viewed using standard 3D ancillary items.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Donna R. Vochmes

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001362